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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,366	02/10/2004	David Hung	12.016011-CON	1188
38732	7590	01/25/2008		
CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			EXAMINER KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER
			1617	
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			01/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/775,366	Applicant(s) HUNG ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' species election without traverse of muscle-relaxing agent as a second agent to be employed is acknowledged. Claims 2-5 have been examined to the extent of Applicants' election.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabar et al.

Tabar et al. on the abstract and page 31 right-hand column, teach an intraductal injection comprising a standard needle (ductal access tool) comprising methylene blue dye and contrast material. Tabar teach that the most difficult step in galactography is gently inserting the blunt needle or cannula into the secreting duct. (page 31, right-hand column) and the procedure is painful. (page 36 middle column).

Tabar et al. do not expressly teach coating tip of a ductal access tool with anesthetic agent.

It would have been obvious to one of ordinary skill in the art to modify the teaching of Tabar et al. and coat the tip of a ductal access tool with an anesthetic agent because the most difficult step in accessing breast duct in galactography is inserting the blunt needle or cannula into the secreting duct and the procedure is very painful as taught by Tabar et al. One would have been motivated to make such a modification in order to achieve an expected benefit to numb the affected breast duct to be treated in order to ease the most difficult step in galactography. There is a reasonable expectation of successfully facilitating ductal access by coating the tip of ductal access

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tool by an anesthetic agent because the procedure of inserting blunt needle or cannula into the secreting duct is painful and the most difficult step in view of Tabar et al.

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabar et al. in view of Stamler et al. (U.S. Patent No. 5,380,758).

Tabar et al. on the abstract and page 31 right-hand column, teach an intraductal injection comprising a standard needle (ductal access tool) comprising methylene blue dye and contrast material. Tabar et al. teach that the most difficult step in galactography is gently inserting the blunt needle or cannula into the secreting duct. (page 31, right-hand column) and the procedure is painful. (page 36 middle column).

Tabar et al. do not teach fluid collection comprising a muscle-relaxing agent and an anesthetic agent to facilitate ductal access or ductal fluid collection or both.

Stamler et al. teach S-nitrosothiol alleviates smooth muscle contraction and spasm and facilitates procedures involving diagnostic instrumentation such as endoscope including fluid aspiration. (abstract, column 9, lines 55-62, column 22, claim 23).

It would have been obvious to one of ordinary skill in the art to modify the method of Tabar et al. and incorporate an anesthetic agent and a muscle relaxing agent to the intraductal injection of Tabar et al. because an anesthetic agent is needed in galactography in intraductal fluid because the procedure is painful and it is difficult to insert the blunt needle into the secreting duct procedure in view of Tabar et al. Moreover, a muscle relaxing agent is useful in fluid aspiration procedure because it

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facilitates and alleviates any muscle contraction or spasm. One would have been motivated to combine an anesthetic and a muscle relaxing agent in an intraductal injection in order to numb the pain and facilitates the procedure involving fluid aspiration in galactography. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.


None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
January 14, 2008